REMARKS

In an Office Action mailed June 30, 2003, the Examiner indicated that Claims 1, 3-11, 15-18, 23-39 and 84-88 are withdrawn from consideration, leaving Claims 45-79 and 89-100 pending in the application. The withdrawn claims are cancelled, without prejudice. All remaining claims depend directly or indirectly from Claim 45.

Claims 45-79 and 89-100 were rejected under 35 U.S.C. §112, first paragraph for an alleged lack of enablement commensurate in scope with the claims. Claims 56-64, 72, 73, 75, 77-79, 89-95, 97 and 99 are rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claims 45-54, 68, 69 and 74 stand rejected under 35 U.S.C. §102(b) as being anticipated by Garson et al. Claims 45-54, 58, 68, 69, 74 and 97 are rejected under 35 U.S.C. §102(e) as being anticipated by Montanari et al.

A prior rejection of Claims 47, 48, 51, 52, 58, 60, 66, 67, 69-71, 73-77 and 80 under 35 U.S.C. §112, second paragraph was withdrawn.

Each issue raised by the Examiner is considered separately below. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112, first paragraph.

The Examiner rejected the pending claims for lack of enablement over the full scope of the claims. The Examiner mentioned that the amounts and identifies of the extracellular matrix compound, the lipid, and the amino acid are not defined. Claims 78, 79, and 89-95 are canceled, so the rejections of those claims are moot.

The specification repeatedly points out that the claimed medicament provides anabolic components to a damaged tissue, noting that the composition of the medicament is principally determined by the molar ratio of amino acids in healthy tissue corresponding to the damaged tissue sought to be treated or to a peptide, polypeptide, or protein of the healthy tissue. The prior recitation of L-amino acids is also amended to reflect that no more than 10% of the amino acids in the medicament are in a dextrorotary (D-) form. Support for this amendment is found in the paragraph bridging pages 9 and 10 of the specification which details the importance of selecting amino acids in a form utilized by the mammalian body to produce proteins. In accord with the invention, D-form amino acids are to be avoided, as these cannot be incorporated into protein chains during protein synthesis. By clarifying both the nature and amount of the amino acid structures in Claim 45, subsequent recitations of achiral amino acids also conform to the independent claim.

Claim 45 also clarifies the nature and amount of the extracellular matrix component in the medicament. The component is a mucopolysaccharide provided in an amount effective for anti-neo-inflammatory and anti-neo-angiogenetic effects in the damaged tissue. Support for these amendments is found in the specification on page 11, in the paragraph beginning at line 10.

These amendments clarify the claims substantially and the applicant believes that the recitations now present in the claims reflect an invention of acceptable scope while providing the skilled person with substantial guidance as to the composition of the claimed medicament. A measure of breadth with regard to the polar surface active lipid is believed appropriate because the polar surface active lipid can range widely, as the specification and subsequent claims demonstrate.

Rejections Under 35 U.S.C. §112, Second Paragraph.

The rejections under §112, second paragraph for indefiniteness are addressed in the amended claims. Claims 78, 79, and 90-95 are canceled and the rejections of these claims are moot.

The alleged lack of clarity in Claims 56, 57 and 61-64 is addressed first by reciting the presence of an alpha-carbon in the plurality of amino acids in Claim 45 and further by additional clarifying amendments to the claims subject to this rejection.

The rejection in Claim 58 and the other claims mentioned in paragraph 7 of the Office Action for recitation of glycine is believed overcome by the aforementioned amendment to Claim 45 that characterizes the plurality of amino acids with reference to the maximum percentage in D form. Those compounds identified as achiral are not in D form and are embraced within the scope of the claims.

Claims 89 and 90-95 were rejected for reference to the molar ratio of amino acids. It is believed that this rejection is overcome, both by the aforementioned clarifying amendment in Claim 45 and by pointing out that the specification offers (e.g., at pages 11-13) several detailed examples of the source of such ratios. The specification further includes a section at pages 16 through 28 that describes a host of formulations and dosages within the scope of Claim 1. As the specification further describes, e.g., at pages 32-34, the individual requirements of a composition for a particular treatment can readily be ascertained and applied. Similarly, the examples on pages 38-43 offer a host of situations in which dosages used in therapy were selected on the basis of the tissue to be treated. The skilled artisan can

also readily determine the amino acid molar ratio of any peptide, polypeptide, protein, or tissue using a standard biology, molecular biology, or medical text.

The wide range of tissues treated with medicaments of the invention and the detail provided in the specification preclude any narrow recitation in the claims of particular tissues. Indeed, such a limitation would deny the applicant the benefit of the breadth of claims to which he is entitled. Surely the examiner cannot require the applicant to specify the amino acid composition of each peptide, polypeptide, protein or tissue in the body. Rather, the applicant has here offered more than a reasonable number of working examples and has stated the principles of the invention such that one skilled in the art can readily apply the principles to any tissue of interest.

Finally, Claim 97, like Claim 58, now recites an achiral compound within the scope of amended Claim 45, thereby eliminating any indefiniteness from the claim.

Rejections under §102.

Claims 45-54, 68, 69, and 74 are rejected under 35 U.S.C. §102(b) as being anticipated by Garson et al. These rejections are respectfully traversed. Each composition disclosed by Garson includes a hydroxy carboxylic acid and Garson discloses no composition that lacks a hydroxy carboxylic acid. The preferred hydroxy carboxylic acid compounds are alpha-hydroxy carboxylic acids, preferably glycolic, lactic, malic, tartaric, citric, and/or mandelic acids, and combinations thereof (col. 1, line 58 et seq). Commonly referred to as alpha-hydroxy acids (AHA), these acids are widely used in cosmetics, notwithstanding lingering questions as to their safety and efficacy.

Amended Claim 45 recites that the medicament is an anabolic (tissue-constructing) medicament, thereby distinguishing the Garson compounds, which are catabolic (tissue-destroying). Hydroxy carboxylic acid compounds cause exfoliation or shedding of surface skin by destroying extracellular matrices. The Examiner will appreciate that the Garson compounds would undermine the targeted regrowth of damaged tissue, whereas the inventive medicaments (as noted, e.g., at page 38), provide anabolic ingredients to encourage protein production and discourage catabolic protein degradation. This aspect of the invention is also noted, in particular, in the paragraph that bridges page 13 and 14. Other instructions to avoid catabolic components are found elsewhere in the specification.

Claims 45-54, 58, 68, 69, 74 and 97 are rejected under 35 U.S.C. §102(e) over Montantari et al. Montantari et al. cannot anticipate the claims it includes no indication that no more than 10% of the amino acids in the medicament are in dextrorotary form, as noted

above. The cosmetic formulation of Montantari is not concerned with protein synthesis, but rather with structural and morphological changes in the hair. As such, Montantari fails to appreciate and does not disclose avoiding D-form amino acids in the compositions. Likewise, there is no indication in Montantari of any effort to provide a plurality of amino acids in a molar ratio corresponding to a tissue, peptide, polypeptide or protein. Finally, Montantari includes no disclosure relating to amounts of mucopolysaccharide extracellular matrix compounds in an anti-neo-inflammatory or anti-neo-angiogenetic effective amount.

For all of these reasons, Montantari does not meet the limitations of amended Claim 45 and its dependents and cannot anticipate the claims.

Having responded to each ground of rejection imposed by the Examiner, the applicant respectfully requests reconsideration of the merits of this patent application. A petition for an extension of time for three months accompanies this response so the response will be deemed to have been timely filed. Applicant is entitled to small entity status.

A Revocation and Appointment of Attorney appointing the undersigned as representative of the applicant accompanies this Response.

Respectfully submitted,

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